REMARKS

This is a full and timely response to the final Office Action mailed July 14, 2006 in the present patent application. Reconsideration of the application in light of the foregoing amendments and the following remarks is respectfully requested.

Status of Claims:

Claims 12-14 and 23-26 were withdrawn under a previous Restriction Requirement and cancelled previously without prejudice or disclaimer. In the present amendment, claim 27 has been rewritten into independent from, and claims 1-3, 7, 9-11, 17-19, 21, 22 and 28 are cancelled without prejudice or disclaimer

Entry and consideration of these amendments is proper under 37 C.F.R. § 1.116 for at least the following reasons. The present amendment does not raise new issues requiring further search or consideration. No claims are added, no new recitations are added to any claim. Consequently, the present amendment merely focuses the application on the key issues at hand, reduces the issues remaining and thus places the application in better form for a possible appeal. Therefore, entry of the present amendment is proper under 37 C.F.R. § 116 and is hereby requested.

Following entry of this amendment, claims 4-6, 8, 15, 16, 20 and 27 are pending for further action.

Prior Art:

The final Office Action maintained a rejection of claims 1-11 and 15-22 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of WO 98/37926 to Schulman et al. ("Schulman") and an article entitled "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain," by Novak et al. ("Novak"). This rejection is rendered moot except as to claims 4-6, 8, 15, 16 and 20 by the cancellation herein of the other rejected claims. As to the claims that remain, Applicant continues to respectfully traverse this rejection for at least the following reasons.

Claim 4 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic pain;
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
> generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and
> delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
> wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
> *wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.*

(emphasis added).

In contrast, the cited combination of prior art references fails to teach or suggest a method of treating a patient with chronic pain including delivering stimulation pulses with a leadless stimulator to *"at least one of an intercostal nerve, an intercostal nerve branch, a greater*

occipital nerve, a lesser occipital nerve, and a third occipital nerve." The final Office Action implicitly concedes that this is the case. The Action is unable to cite to any portion of the prior art that actually teaches or suggests the claimed method including delivering stimulation pulses to the specific target nerves listed.

Rather, the final Office Action addresses claim 4 as follows. "[B]ecause Shulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation." (Action of 7/14/06, p. 3). In response, it should be noted that claim 4 does not merely recite implanting a device near any peripheral nerve. In this regard, the final Action fails to actually address the specific recitations of claim 4.

Claim 4 actually recites a method of treating a patient with chronic pain including delivering stimulation pulses with a leadless stimulator to at least one of "*an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.*" The final Office Action fails to address these specific nerve sites or to argue how and where the prior art teaches delivering stimulation pulses at these specific nerve sites to treat chronic pain.

Rather, the Action appears to take the position that because the prior art teaches stimulating certain nerves to treat non-chronic pain, it would be obvious to stimulate any other nerve site to treat chronic pain. (Action of 7/14/06, p. 5). This is clearly reading far too much into the prior art. One of ordinary skill in the art, e.g., a physician, would never make such a leap in reasoning.

The teachings of the prior art can be extended, as Applicant has done. However, such extension requires careful experimentation and discovery, i.e., patentable invention. This is what Applicant has achieved.

Referring again to the Office Action, the Action argues that "it would have been obvious to implant the device near a peripheral nerve *if the peripheral nerve required stimulation.*" (Action of 7/14/06, p. 3) (emphasis added). This statement illustrates the leap in reasoning being made by the Action. How does one determine "if the peripheral nerve require[s] stimulation?" The Action fails to answer this question.

Rather, according to the Action, the "type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides." (Action of 7/14, 06, p. 3). If this is an allegation that one of skill in the art would, based on prior art teachings, obviously modify the teachings of Schulman and Novak to deliver stimulation pulses at the nerve sites claimed by Applicant, Applicant respectfully requests that prior art be cited to support this conclusion. Applicant notes that "[t]he examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert*, 424 F. 2d 1088, 165 USPQ 418, 420 (CCPA 1970). .. . [However, if] the applicant traverses such an assertion the examiner should cite a reference in support of his or her position." M.P.E.P § 2144.03.

The bottom line is that the cited prior art does not teach or suggest the claimed method of treating a patient with chronic pain by delivering stimulation pulses with a leadless stimulator to at least one of "an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser

occipital nerve, and a third occipital nerve." The final Action fails to indicate how or where the prior art teaches delivering the claimed stimulation pulses to the specific nerve sites claimed.

> MPEP 2131 further states:
> "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). Schulman does not teach or suggest a method of stimulating nerves that include any of the nerves now recited in claim 4. Novak likewise does not teach or suggest a method including stimulation of any of the nerves now recited in claim 4. Consequently, the applied prior art, taken alone or in combination, does not teach or suggest the method of claim 4.

It is incumbent upon the Office to cited prior art that actually teaches the subject matter of Applicant's claims. M.P.E.P. § 706.02(j). In the present case, the prior art of record does not teach or suggest the method of claim 4 including the specific stimulation sites recited for the purpose of treating chronic pain. For at least these reasons, the rejection of claim 4 should be reconsidered and withdrawn.

Claim 8 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic pain;
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

(emphasis added).

The final Office Action does not address the details or specific recitations of claim 8. Rather, the final Action merely states that "all of the above comments made in support of the rejection of similarly worded limitations apply here as well." (Action of 7/14/06, p. 4). However, there has been no other claim in this application that also recites the subject matter emphasized above in claim 8. Rather, as with other claims in this application, the Office Action chooses to simply overlook some of the limitations recited.

Claim 8 recites a method of treating chronic pain with an implanted stimulator that stimulates at least one of a list of specific nerve sites. In contrast, neither Schulman nor Novak teach or suggest a method including stimulation of any of the listed nerves to treat chronic pain. The final Office Action fails to address these particular nerve site or to explain how or why it would be obvious from the prior art to stimulate these particular nerve sites to treat chronic pain as in the method of claim 8.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180

USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 8 should be reconsidered and withdrawn.

Independent claim 15 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic peripheral pain, *wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain*;
> providing at least one leadless stimulator having at least two electrodes;
> providing at least one sensor;
> implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;
> providing operating power to the at least one stimulator;
> using the sensor to sense a physical condition;
> determining stimulation parameters based upon the sensed condition;
> generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and
> delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
> wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient. .

(emphasis added).

In contrast, neither Schulman nor Novak teach or suggest the claimed method for treating chronic pain which includes "at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain." These maladies are not even mentioned by Schulman or Novak. Nor would it have been obvious to one of skill in the art to take the teachings of Schulman and Novak and apply them to an entirely different group of patient conditions requiring stimulation at entirely different nerve

locations. This subject matter simply is not taught or suggested by Schulman and Novak and clearly represents a patentable advance over those teachings.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 15 and its dependent claims should be reconsidered and withdrawn.

Claims 27 and 28 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Schulman, Novak and U.S. Patent No. 6,480,745 to Nelson et al. ("Nelson"). This rejection is moot as to claim 28 which was cancelled herein without prejudice or disclaimer. As to claim 27, this rejection is respectfully traversed for at least the following reasons.

Claim 27 recites:

> A method for treating a patient with chronic pain, comprising:
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
> generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters;
> delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
> transmitting data from a transmitter of said stimulator to an external device; and
> *transmitting said stimulation parameters to said external device.*

(Emphasis added).

In contrast, the cited combination of prior art fails to teach or suggest a method in which an implanted stimulator transmits its stimulation parameters to an external device. In this regard, the final Office Action refers to Nelson at col. 2, lines 39-67. (Action of 7/14/06, p. 4). This portion of Nelson reads as follows:

> After the implantation of an IMD, for example, a cardiac pacemaker, clinician involvement with respect to the IMD has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings, or even replacement, in response to or in anticipation of changes in patient condition or other environmental factors, or based on factors internal to the device. IMDs may also contain logic devices such as digital controllers, which may need to undergo firmware or software upgrades or modifications. In addition, information about the IMD may be gathered for treatment or research purposes. For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data.
>
> Because IMD operation and patient physiology is preferably monitored to help effect the desired patient outcome, it would be desirable if data collected by an IMD could be viewed remotely. Similarly, it would also be desirable that the instructions installed in an IMD may be modified in response to patient physiologic information, or perhaps be upgraded remotely as well.
>
> In the event a change, modification or reprogramming of the IMDs is indicated, it would be desireable if the instruction could be implemented in the IMD as soon as possible, thus providing more continuous monitoring to proactively effect changes in the IMDs for efficient therapy and clinical care. This scenario may be contrasted with existing practice of responding to an adverse patient event or subjecting the patient to the inconvenience or expense of frequent in-person encounters with a clinician, for example after an unexpected therapy by the device, or to effect other monitoring of device functioning, e.g., spontaneous therapies by the device. For example, an implanted cardioverter defibrillator may administer to the host patient a cardioversion or defibrillation therapy. After such therapy, it is typically desirable to determine the parameters of, for example, an arrhythmia that a therapy was administered in response to, or of the therapy administered.

(Nelson, col. 2, lines 39-67).

This portion of Nelson does not teach or suggest that the implanted device transmits its own stimulation parameters to an external device as recited in claim 27. To the contrary, Nelson

appears only to teach that "patient physiologic data detected by a deployed IMD 112 will be transmitted via IMDNI 116 to computer 220 for purposes of analysis of this data." (Nelson, col. 11, lines 13-15). This patient physiologic data may be used to decide on a change to stimulation parameters and an instruction to make that change may be transmitted to the stimulator. (Nelson, col. 11, lines 16-18). However, Nelson does not ever teach or suggest that the current stimulation parameters are transmitted by the implant to an external device as recited in claim 27.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 27 should be reconsidered and withdrawn.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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